

## **REMARKS**

### **I. Status of Claims**

This application has been further reviewed in light of the Office Action dated March 23, 2004. Claims 1-30 are pending in the application. By the present amendment, claims 1, 6, 9-10, 12, 23, 29 and 30 are amended in a manner, which is believed to overcome the rejections in the Office Action.

### **II. Double patenting over claims 1-75 of U.S. Patent No. 6,180,132**

A rejection was made to claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,180,132 (the '132 patent). Applicants respectfully submit that the claimed subject matter of the rejected claims differ from that of the claims within the '132 patent. Specifically, several rejected claims are directed to a variety of additives that are not found within the '132 patent. Further, other rejected claims are directed to shapes and methods of use of the self supporting hydrogel that are also not found within the '132 patent. In order to facilitate the passage of the instant application to allowance Applicants have attached to this response an executed terminal disclaimer.

### **III. Claims 1-30 rejected under 35 U.S.C. 112, second paragraph.**

The Examiner rejected claims 1-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

Regarding claims 1, 12 and 23, the Examiner stated that the expression "accelerator" does not set out the metes and bounds of the claimed invention. The Examiner further stated that recourse to the specification does not define the expression "accelerator." Applicants respectfully traverse this rejection and would direct the Examiner's attention to the instant specification page 8 lines 17-19 where "accelerator" is defined as being selected from the group consisting of sodium carbonate, carbonate salts, sodium hydroxide, sodium citrate, potassium phosphate, ammonia, and polyalkoxyamines such as polyetheramine. Applicants respectfully

submit that one skilled in the art would clearly understand the metes and bounds of the claims as to the expression “accelerator” and respectfully request that this rejection be withdrawn.

Regarding claim 6, the Examiner stated that the expression “other antimicrobial and other additives” does not set out the metes and bounds of the claimed invention. Applicants have amended claim 6 and respectfully submit that this rejection has been overcome.

Regarding claims 9 and 10, the Examiner stated that the phrase “such as” renders the claim indefinite. Applicants have amended claims 9 and 10 and respectfully submit that this rejection has been overcome.

Regarding claims 29 and 30, the Examiner stated that there is insufficient antecedent basis for the limitation “dressing.” Applicants have amended claims 29 and 30 and respectfully submit that this rejection has been overcome.

#### **IV. Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. §102(b)**

Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. §102(b) as being anticipated by Cartmell et al. U.S. Patent No. 5,160,328, (“Cartmell”). Applicants respectfully traverse this rejection.

The Examiner stated, in rejecting previous arguments of Applicants, that the recitation of the intended use in the claim preamble does not limit the scope of the claim and that the composition disclosed by the prior art has the same ingredients in the same amounts as the instant claims and inherently will have the same physical properties such as resiliency.

Applicants respectfully submit that the hydrogel of Cartmell does not have the “self supporting resilience” of the instant application as it has a different composition. Unlike Applicants’ claimed invention, the hydrogel of Cartmell does not include “from 3 percent to 45 percent by weight of one or more alkyl diols” as Applicants have disclosed and claimed in amended claim 1. Applicants have also amended independent claims 12 and 23 to further define Applicants’ hydrogel as being formed from a first solution and a second solution, wherein the second solution comprises water, “an alkyl diol” and accelerator.

Applicants respectfully submit that the method of claim 12 and the composition containing an “alkyl diol” produced according to this method are not disclosed or suggested in Cartmell, and accordingly are not anticipated under 35 U.S.C. §102(b).

Claim 23 has been amended to further define that Applicants' hydrogel contains "an alkyl diol" that allowing for a "self supporting resilient hydrogel" composition having a thickness of approximately 2.0 to 2.5 cm. This thickness range is outside that which is found in the Cartmell patent, which discloses a composition from 0.6 to 1.5 cm thick. Furthermore, the composition that allows the self supporting resilient nature of Applicants' claimed invention is not taught or suggested in Cartmell. Claims 18, 20, 22, 24, 25, 26, 27, 29 and 30 are directed to various shapes that are molded for a variety of uses. These various shapes and uses are not possible with a non-self supporting hydrogel. Applicants respectfully submit that the "self supporting resilient hydrogel" required by the shapes in the above claims is not disclosed or suggested by Cartmell.

Applicants respectfully submit that the claimed compositions and methods of producing those compositions are not anticipated by Cartmell under 35 U.S.C. §102(b). As has been clearly enunciated by the Federal Circuit: Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 221 USPQ 481, 485 (Fed Cir. 1984) (emphasis added). Here the requirement of showing each and every element of Applicants' claimed invention has not been met, as Cartmell fails to disclose or teach a hydrogel having the composition containing an alkyl diol that is self supporting as disclosed and claimed by the Applicants. It is respectfully requested that these rejections based upon 35 U.S.C. §102(b) be withdrawn.

#### **V. Claims 2-11 and 15-17 are rejected under 35 U.S.C. §103(a)**

Claims 2-11 and 15-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cartmell in view of Hennink et al. (U.S. Patent No. 5,219,325, "Hennink") or Hare et al. U.S. Patent No. 4,846,165 ("Hare"). The Examiner stated that Cartmell did not teach the specific antimicrobial agents as claimed by Applicants. Hare teaches a wound dressing comprising polyurethane, polyethylene glycol, filler and therapeutic agents. Hennink teaches hydrogel wound dressing composition that comprises ingredients to absorb fluids and promote healing of a wound. The Examiner stated that it would have been obvious to one having ordinary skill in the art to provide a composition useful for wound dressing comprising polyurethane and glycol as

disclosed by Cartmell and to add antimicrobial agents to the composition as disclosed by Hennink and Hare. Applicants respectfully traverse this rejection.

As noted above, the hydrogel composition of Cartmell does not have the same composition as the instant disclosed and claimed invention. Unlike Applicants' claimed invention, the hydrogel of Cartmell does not include "from 3 percent to 45 percent by weight of one or more alkyl diols" as Applicants have disclosed and claimed in claim 1 from which claims 2-11 depend and independent claim 12 from claims 15-17 depend. The composition of Cartmell does not include an alkyl diol and does not have advantageous strength, and therefore, it requires a substrate for support, unlike the instant disclosed and claimed invention.

Claim 12 as amended emphasizes that the "self supporting resilient" hydrogel wound dressing of the instant invention has "an alkyl diol" allowing for sufficient mechanical strength to be applied to a wound without requiring support by a substrate material or support layers. Cartmell, Hare or Hennink considered alone or in combination, do not teach or suggest Applicants' invention including all of elements of claim 1 and amended claim 12 as described above.

Furthermore, the disclosure of the present invention at page 10, line 17 to page 11, line 9 teaches the unexpectedly superior results achieved by the composition of the present invention, for instance, strength and flexibility, transparency and water absorption characteristics, all of which are not achieved or suggested by the different compositions of Cartmell, Hare and/or Hennink.

The Examiner states that use of the agents disclosed by Hennink and Cartmell to obtain a hydrogel composition containing such agents for the purpose of controlling infection in opened wounds is obvious. However, in the instant case, neither cited reference contains a composition allowing for a self supporting resilient hydrogel or a self supporting resilient hydrogel having the pharmaceutical agents as Applicants have disclosed and claimed. Since the composition of the self supporting nature of the inventive hydrogel and the agents contained therein are not found in the art, it is fair to assume that in raising the obviousness rejection, the Examiner gleaned knowledge from Applicants' disclosure, contrary to well-established legal principles. Applicants respectfully request that the rejected claims be favorably reconsidered in light of well-established legal principles, which provide,

*"That one skilled in the art is not synonymous with obviousness.... That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the reference to make the claimed invention" Ex parte Levengood, 28 USPQ 2d 1300 (Bd. Pat. App. & Inter. 1993).*

The particular combination of the cited references, which the Examiner makes in an attempt to arrive at the Applicants' invention, is neither taught nor suggested by any of the references. The references, alone or in combination, because of each featured difference, as discussed above, do not provide "sufficient impetus" to support the combination that the Examiner makes to effect the obviousness rejection. Furthermore, the combination that the Examiner suggests does not arrive at the Applicants' invention.

Applicants therefore respectfully submit that claims 2-11, which depend from amended claim 1, and claims 15-17, which depend from amended claim 12, are not obvious under 35 U.S.C. §103(a) over Cartmell in view of Hennink or Hare. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VI. Claims 1-11 and 23-30 are rejected under 35 U.S.C. §103(a)**

Claims 1-11 and 23-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reich et al. U.S. Patent No. 5,932,200 ("Reich") in view of Hennink et al. (U.S. Patent No. 5,219,325, "Hennink") or Hare et al. U.S. Patent No. 4,846,165 ("Hare"). The Examiner stated that Reich does not reach the specific antimicrobial agents as claimed by Applicants, or the amount of different ingredients in the composition, however, the amounts of different ingredients do not impart patentability to the composition claims, absent evidence to the contrary. Applicants respectfully traverse this rejection.

Reich teaches a resilient hydrogel that comprises polyurethane, alkyl diol selected from ethylene glycol and propylene glycol, water, colors and fragrance. Unlike the Applicants disclosed and claimed invention the hydrogel of Reich does not teach using "from 3 percent to 45 percent by weight of one or more polyalkyl diols selected from the group consisting of

polyethylene glycol, polypropylene glycol and polybutylene glycol,” as Applicants have disclosed and claimed. The hydrogel of Reich contains a different composition than the instant disclosed and claimed hydrogel. The composition of the hydrogel of Reich and the diol used is described as follows:

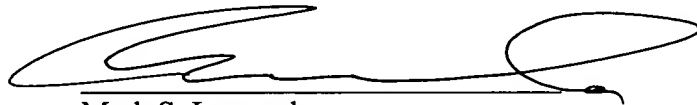
“a long chain polyoxyethylene glycol optionally mixed with a low molecular weight polyoxyethylene glycol, polyoxypropylene glycol having a average molecular weight of about 200 to about 4,000, polyoxtetramethylene glycol having a number average molecular weight of about 200 to about 4,000, polyether polycarbonate having a number average molecular weight of about 400 to about 3,000, a low molecular weight alkylene glycol selected from ethylene glycol, propylene glycol 2-ethyl-1,3hexanediol, tripropylene glycol, triethylene glycol, 2, -4pentanediol, 2-methyl-1,3-propanediol, cyclohexanediol, cyclohexanedimethanol, 2-methyl-1,3-pentanediol dipropylene glycol and diethylene glycol, and mixtures thereof having a number average molecular weight of about 1,000 to about 9,000, an organic diisocyanate and a water equivalent in an amount comprising from about 0.001% to about 0.8% of the reaction mixture in an equivalent mole weight ration of NCO/OH” (Reich at column 2 lines 41-60).

The differences in the composition of the instant claimed and invention and that of Reich are further highlighted as follows: “Preferably, the diol is polyoxyethylene” (Reich at column 2 line 64). Applicants respectfully submit that the hydrogel composition of the instant claim invention is not taught or suggested by Reich and respectfully requests that this rejection be withdrawn.

## CONCLUSION

Accordingly, it is believed that in view of the above comments and further amendments to the claims, all claims are now in condition for allowance, and therefore reconsideration and allowance are earnestly solicited. If the Examiner feels that a further telephone conference would expedite allowance/issuance of this case, or resolve any remaining or other issues, the Examiner is invited to contact the undersigned at (617) 856-8145.

Respectfully submitted,



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